US ERA ARCHIVE DOCUMENT

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Q9-5708 "ntimierobial Agent 10740/ 17 3(trimethoxysily/) propyldimethylociadecyl ammonium ehloride - 42%

DOW CORNING 5700 ANTIMICROBIAL AGENT - Caswell No. 892 B

Date: April 19, 1979

Present: Dr. M. Adrian Gross - Tox

Dr. S.L. Chan - Tox Dr. R. Engler - Dis Ms. D. Jenkins - Dis Mr. E. Brown - Dis Mr. J. Lee - Dis OPP OFFICIAL RECORD HEALTH EFFECTS DIVISION SCIENTIFIC DATA REVIEWS EPA SERIES 361

Date requirements for a hazard assessment were discussed, in light of over 10 registration amendments (end use). Dow Corning in their letter of April 6, 1979, has requested guidance.

- l. The adsorption of the compound should be studied using radioactivly labeled technical compound. Adsorption by normal skin, and mucous membranes should be studied. The study should also provide a quantitative measure of the fate of the compound. The exposure level should not in itself cause dermal damage, but should be high enough to provide meaningful metabolism/skin transport data. If significant adsorption should occur, long term-, reproduction-, teratology- and mutagenicity studies must be done. It was recognized that an adsorption study with the technical compound (not adhering to fiber) may not accurately reflect the use situation. But it was also recognized that conclusively showing zero adsorption from treated fabric maybe very difficult, if not impossible.
- 2. The compound may cause human health effects by changing the dermal and vaginal microflora. Controlled animal studies should be carried out to determine that such changes in microflora do not occur.
- 3. Impregnated lint particles may pose an eye irritation hazard. This possibility must be ruled out by an appropriate eye irritation study.
- 4. The issue of IBT studies was not specifically addressed but it is self-evident that past and future studies must meet scientific criteria for acceptability. Furthermore, Agency scientists are available for discussion of protocols of any prospective studies.

5. The conclusions reached can serve as a generic approach to other bacteriostatic agents used for human appreal impregnation.

cc: Dr. Chanl Dr. Gross (Adrian)

Mr. Lee Mr. Brown



046787

Chemical:

1-Octadecanaminium, N,N-dimethyl-N-(3-(t

PC Code:

107401

HED File Code

13100 Other Tox Documents

Memo Date:

04/19/79

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